K 122411

FEB 1 1 2013

510(k) SUMMARY

Applicant:	Myelotec, Inc 4000 Northfield Way Suite 900 Roswell, GA 30076 USA 404-355-4485
Contact:	Richard Wunderlich CEO
Date Prepared:	July 25, 2012
Predicate Device:	Henke Sass Wolf Arthroscope, K080560
Device Identification:	Trade Name: J-Scope Tissue Visualization & Assessment Mini-Cannula Kit and J-Scope Tissue Visualization & Assessment Arthroscope
Common Name:	The J-Scope System
Classification Name:	Orthopedic—Arthroscope: 21 CFR 888.1100 Class II
Product Code:	HRX
Device Description:	The J-Scope Tissue Visualization & Assessment Mini-Cannula Kit is a single-use, disposable small diameter, 14-gauge needle mini-cannula device which, when coupled with the J-Scope semi-rigid or flexible Arthroscope, provides convenient and precise arthroscopic visualization of both major and minor joints. The micro-invasive design of the system allows the procedure to be performed comfortably with the patient under local anesthesia.
Intended Use:	The J-Scope System is an endoscopic device intended to be used by physicians for introduction of fluids to assist in visualization of intra-articular structures for arthroscopic diagnosis, as well as for surgical procedures using a second J-Scope or other arthroscopic device. It is indicated for use in the shoulder, hip, wrist, ankle, knee, and elbow joints.
Substantial Equivalence:	The J-Scope System is substantially equivalent to the predicate device as the basic features, functionality, and intended uses are similar. The minor differences raise no new issues of safety and effectiveness and

have no effect on the performance, function, or intended use of the device.

Technological Characteristics:

The J-Scope System is very similar to the Henke Sass Wolf Arthroscope in design and function. Both the subject and HSW predicate devices make use of the same, or similar, technology. The trocar sheaths, obturators, and trocars are made of stainless steel, and access ports are provided on the trocars for flushing with saline. The J-Scope differs from the HSW Arthroscope in that the cannula body and handles are made of various plastics such as polycarbonate and polyethylene while the HSW cannula is made of stainless steel and is autoclavable. The arthroscopes are very similar in design and materials.

Testing:

The J-Scope was tested for conformance with the following performance standards: ISO 10993: Biological Evaluation of Medical Devices, IEC 60601-2-18 - Medical Electrical Equipment – Particular requirements for the safety of endoscopic equipment, ISO 11135-1:2007, Sterilization of Health Care Products— Ethylene Oxide, reference 7.1, Product Adoption and Process Equivalency for Ethylene Oxide Sterilization, and EN60601-2-18, Medical Electrical Equipment – Particular requirements for the safety of endoscopic equipment. In addition, Expiration Dating tests were performed, as was system component validation testing.

Conclusion:

The technological differences between the HSW Arthroscope and the J-Scope System do not raise any new questions of safety or effectiveness and testing demonstrates that the J-Scope is as safe and effective as the predicate devices. Therefore the J-Scope System is substantially equivalent to the previously cleared Henke Sass Wolf Arthroscope (K080560).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Myelotec
% Tamm Net, Incorporated
Mr. Blix Winston, MPA, MS
Director, Regulatory Affairs
2600 Mullinix Mill Road
Mount Airy, Maryland 21771

February 11, 2013

Re: K122411
Trade/Device Name: J-Scope Tissue Visualization & Assessment Mini-Cannula Kit and J-Scope Tissue Visualization & Assessment Arthroscope
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: December 17, 2012
Received: December 26, 2012

Dear Mr. Winston:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122411

Device Name:

J-Scope Tissue Visualization & Assessment Mini-Cannula Kit and
J-Scope Tissue Visualization & Assessment Arthroscope

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H. Chen -S

Digitally signed by Long H. Chen -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -S, 0.9.2342.19200300.100.1.1=1300369056
Date: 2013.02.11 11:52:15 -05'00'

(Division Sign-Off)
Division of Surgical Devices
510(k) Number ___K122411_____